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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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LEGISLATION AND REGULATION COMMITTEE

Regulation Report

NO ACTION

Regulation Update

Rulemaking Activity

Staff published a 15-day notice on February 2, 2005 to make minor change to the omnibus group of regulations approved by the board at the January 2005 board meeting. That notice period ended on February 22, 2005. There were no changes or comments to made to this language.

The rulemaking package is now undergoing administrative review. The regulations should be in place before the July 2005 board meeting. A copy of the language is provided in Attachment 1.

Pending Regulations

At the October 2004 Board meeting, the board moved to regulation hearing proposed regulation changes that will permit the use of drop boxes to drop off prescriptions, and the use of automated dispensing devises to dispense refill medication when the patient has "opt-in" to use this system. At the current time, the regulation has not been noticed. A copy of the language is provided in Attachment 2.

Attachment 1

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Board of Pharmacy
Order of Adoption

California Code of Regulations, Title 16

§1706.2. Abandonment of Application Files.

(a) An applicant for a ~~permit~~ license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy ~~manufacturer,~~ wholesaler, ~~supplier,~~ out-of-state distributor, or clinic~~, medical device retailer or warehouse of a medical device retailer~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements ~~which are~~ in effect at the time of reapplication.
(b) An applicant for a pharmacy technician license ~~registration~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4029, ~~4033, 4034,~~ 4037, 4043, 4110, 4112, 4115, 4120~~,~~ 4127.1, 4160, 4161, 4180, 4190, ~~and~~ 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

§1712. Use of Pharmacist Identifiers.

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.
(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy.

Note:

Authority cited: sections 4005, Business and Professions Code. Reference: sections 4005 and 4115, Business and Professions Code.

§1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new pharmacy permit has been issued, or
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
(c) The components of this assessment shall be on Form 17M-13 ~~17I-29 (Rev 1/01)~~ entitled "Community Pharmacy & Hospital Outpatient Pharmacy ~~and Practice~~ Self-Assessment ~~(Including Hospital Pharmacy That Dispenses Prescriptions)~~" or Form 17M-14 ~~17I-30 (Rev 1/01)~~ entitled "Hospital ~~Inpatient~~ Pharmacy ~~and Practice~~ Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations. ~~regarding: facility condition and security, drug stock, posting of certificates and notices, pharmacist-in-charge obligations, intern pharmacist activities, pharmacy technician activities, general pharmacy practice, corresponding responsibility for filling controlled substances provisions, prescription requirements, prescription labeling and dispensing, refill authorization, prescription transfers, confidentiality of prescriptions, record keeping requirements for all dangerous drugs, record keeping requirements for controlled substances, automated dispensing devices, repackaging for use by the pharmacy, compounding unapproved drugs for future use or prescriber office use, electronic transmission of prescriptions.~~
(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, ~~4133,~~ 4305, 4330, 4332 and 4333, Business and Professions Code.

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code s~~S~~ection 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

Chart orders as defined in ~~S~~section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code ~~S~~section 4005.

(e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.

(f) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

(g) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note:

Authority cited: ~~S~~sections 4005, 4075 and 4114, Business and Professions Code. Reference: ~~S~~sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Article 3. ~~Licentiates in Pharmacy~~ Pharmacist Candidates

§1719. ~~Requirements for Admission to Examination.~~ Recognized Schools of Pharmacy.

As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

~~(a) Applicants for the pharmacist licensure examination shall have completed all requirements for graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the Board.~~

~~(b) All candidates for the pharmacist licensure examination shall have completed a minimum of 1,000 hours of experience prior to applying for the examination.~~

~~(c) All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections ~~851, 4005~~ ~~and~~ 4200 of the Business and Professions Code.

§1720. Application for Pharmacist Examination and Licensure. ~~Registration.~~

(a) An application for examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.

(b) The fee required by ~~Section 1749,~~ subdivision (d) of section 1749 of this Division shall be paid for each application for initial examination and for any application to retake the examination described in section 4200.2 of the Business and Professions Code. The fee is nonrefundable.
(c) ~~An applicant who fails to pay the fee required by Section 1749, subdivision (f) within one year after being notified of his or her eligibility for a license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication.~~
~~(d)~~ Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.
~~(e) An applicant for examination who does not take the examination within one year of the date the applicant is determined by the board to be eligible to take the examination shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~Section~~ sections 4200 and 4200.2, Business and Professions Code.

§1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate ~~Examination~~ Equivalency Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a). Candidates who have been certified by the Foreign Pharmacy Graduate Equivalency Committee before January 1, 1998, must also provide the board with a score on the Test of Spoken English of least 50. For candidates who took the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.
~~(a) Each applicant for admission to the pharmacist licensure examination, whose eligibility is based upon the provisions of Business & Professions Code section 4200(a)(2)(B), shall be required to demonstrate that the education obtained at the foreign school is equivalent to that required of domestic graduates by receiving a grade satisfactory to the board on the Foreign Pharmacy Equivalency Examination administered by the National Association of Boards of Pharmacy.~~
~~(b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an applicant's collegiate equivalency pursuant to Business and Professions Code section 4200(a)(3). If the applicant cannot provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include authentication, translation and or evaluation of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~Section~~ sections 851 and 4200, Business and Professions Code.

§1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a ~~pharmacy~~ recognized school of pharmacy. ~~approved by the American Council on Pharmaceutical Education or recognized by the board.~~
(b) A final examination must be a part of the course of study.
(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4200.1, Business and Professions Code.

§1726. ~~Preceptor.~~ Supervision of Intern Pharmacists.

(a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision.~~A preceptor is a pharmacist registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.~~
(b) The ~~preceptor~~ pharmacist supervising an intern pharmacist shall ~~supervise the intern's activities to~~ provide the experience necessary ~~to make~~ for the intern pharmacist to become proficient in the practice of pharmacy. ~~provision of pharmaceutical services.~~
~~(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4030, 4114 and 4200, Business and Professions Code.

§1727. Intern Pharmacist.

~~(a) An intern pharmacist is a person who holds a valid intern card.~~
~~(b) An intern card shall be issued for a period of:~~
~~(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.~~
~~(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.~~
~~(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.~~
~~(4) One year to an out-of-state licentiate who is awaiting the administration of the next licensure examination.~~

~~(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:~~

~~(1) Persons who have not completed experience requirements.~~

~~(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.~~

~~(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.~~

~~(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4030, 4114 and 4200, Business and Professions Code.

§1728. ~~Intern Experience--~~Requirements for Examination. ~~Licensure.~~

~~(a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure.~~

~~(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.~~

~~(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.~~

~~(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.~~

~~(b) Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:~~

~~(1) Receiving and interpreting the prescription;~~

~~(2) Patient medication profiles;~~

~~(3) Prescription preparation;~~

~~(4) Consultation;~~

~~(5) Record keeping;~~

~~(6) Over the counter products;~~

~~(7) Drug information.~~

~~(c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.~~

~~(d) Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.~~

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the boar to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note:

Authority cited: ~~S~~sections 851, and 4005 ~~and 4114~~, Business and Professions Code. Reference: ~~S~~sections 144, 851, ~~4114~~ and 4200, Business and Professions Code.

§1732. Definitions.

As used in this article:

(a) ~~An accreditation~~ "Accreditation agency" means ~~is~~ an organization which evaluates and accredits providers of continuing ~~pharmaceutical~~ education for pharmacists. ~~, monitors the quality of their educational activities, and audits continuing education coursework.~~

(b) ~~The American Council on Pharmaceutical Education (ACPE) is the national accrediting agency for providers of continuing pharmaceutical education.~~

~~(c) The Accreditation Evaluation Service is the continuing education provider and coursework review component of the California Pharmacists Association.~~

~~(d) A recognized provider is anyone whose qualifications as a continuing education provider have been approved by an accreditation agency approved by the Board.~~

~~(e) An hour consists of~~ "Hour" means at least 50 minutes of contact time.

(c) "Provider" means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved ~~by the Board~~ as ~~continuing education and~~ accreditation agencies:

(1) The Accreditation Council for Pharmacy Education. ~~American Council on Pharmaceutical Education~~

(2) The Pharmacy Foundation of California. ~~Accreditation Evaluation Service of the California Pharmacists Association~~

(b) ~~Upon written application to the Board, any other organization will be approved by the board if:~~ Accreditation agencies shall:

(1) ~~the organization submits a plan demonstrating that it has the capacity to evaluate~~ Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

~~following criteria:~~

~~(A) Topics and subject matter shall be pertinent to the practice of pharmacy as specified in section 4232 of the Business and Professions Code and section 1732.1(c) of the California Code of Regulations.~~

~~(B) Each continuing education course shall have written educational goals and specific learning objectives which are measurable and which serve as a basis for an evaluation of the program's effectiveness.~~

~~(C) Speakers shall be competent in the subject matter and shall be qualified by education, training and/or experience.~~

~~(D) Each continuing education course shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the instructional objectives for each course and a summary containing the main points for each topic.~~

~~(E) When an approved provider works with others on the development, distribution and/or presentation of continuing education programs (joint sponsorship), there shall be procedures to identify and document the functions of each participating party.~~

~~(F) Promotional materials shall meet the requirements specified in section 1732.3(d) of the California Code of Regulations. Advertisements shall also include at least the following:~~

~~1. the educational goals and specific learning objectives of the program.~~

~~2. the nature of the targeted audiences that may best benefit from participation in the program.~~

~~3. the speakers and their credentials.~~

~~(G) An evaluation mechanism shall be used. The mechanism shall allow all participants to assess their achievement in accordance with the program's learning objectives. Self-evaluation mechanisms may include, but are not limited to, pre- and post-testing, pre-testing along with group discussion and critique of answers, patient case-study discussions and problem solving exercises. The provider shall also develop a mechanism for each participant to evaluate the continuing education course.~~

~~(H) Where the method of educational delivery does not translate into contact hours, such as home study programs and other mediated instructional approaches, there shall be procedures for the determination of hours of credit for~~

~~courses. Procedures used to determine the amount of time required for participants to successfully complete the program shall be documented and defensible. Acceptable procedures include:~~

~~1. assessing the amount of time the activity would require if it were delivered in a more formal and structured live program format; or,~~

~~2. pilot testing the activity with a group of pharmacists who are representative of the target audience and ascertaining the mean average length of time for completion for only those participants who successfully complete the program; or,~~

~~3. determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of continuing education.~~

~~(I) The provider shall be required to maintain records of each enrollee's participation in continuing education programs.~~

~~1. For live programs, acceptable documentation of participation includes attendance rosters, sign-in sheets, completed program evaluation forms, or signed verification forms.~~

~~2. For home study and other mediated instructional approaches--acceptable documentation of participation includes:~~

~~a. use of a post-testing procedure in which a pre-established proficiency level is established and certificates are awarded only upon attainment of the pre-specified minimum proficiency level;~~

~~b. in the case of study groups, the successful completion of the program may be attested to by all participants; or~~

~~c. completion and submission, by the individual participant, of a written evaluation or critique of both the program and its applicability to the participant's practice of pharmacy. The evaluation shall be of sufficient length and detail to demonstrate successful completion of the program and a reasoned consideration of its applicability to the participant's professional practice.~~

(2) ~~The organization agrees to perform the following:(A)~~ Maintain a list of the name and address ~~names and addresses~~ of the ~~persons designated as~~ person responsible for the provider's ~~C.E.~~ continuing education program. The accreditation agency shall require that any change in the ~~designated~~ responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the ~~of such~~ change.

~~(B) Notify the Board of~~

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

~~(C)~~

(4) Respond to complaints from the board ~~Board~~, providers or from ~~California~~ pharmacists concerning activities of any of its ~~approved~~ accredited providers or their coursework.

~~(D)~~

(5) Review at least ~~a ten percent (10%) sample of coursework, as determined by the Board, but not less than~~ one course per year offered by each provider ~~approved~~ accredited by the agency for compliance with the agency's requirements and requirements of the board ~~Board~~ and, on request, report the findings of such reviews to the board ~~Board~~.

~~(E)~~

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the boardBoard; and

(F) (7) Verify the attendance of licentiates completion at of a specific continuing education course by an individual pharmacist presentations upon request of the board this article.the Board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b)(1) or to perform in accordance with the terms of its agreement as described in (b)(2) shall constitute cause for revocation of its approval as an accreditation agency by the board Board.

Note:

Authority cited: Ssection 4005, Business and Professions Code. Reference: Ssection 4232, Business and Professions Code.

§1732.1. Requirements for ~~Recognized~~ Accredited Providers.

(a) Anyone seeking to provide continuing education courses as a recognized provider for California pharmacists shall apply to a Board approved accreditation agency for recognition as a provider prior to offering any such courses. No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to section 1732.2 of this Division.

(b) Providers shall ensure that each continuing education course complies with the requirements of section 1732.3 of this Division.

Upon satisfactory completion of the accreditation requirements of the accreditation agency and receipt of written approval therefrom, a continuing education provider may represent itself as a California recognized provider of continuing education material for pharmacists.

(c) The provider is responsible for assuring the educational quality of its coursework. Coursework shall be relevant to the practice of pharmacy and shall be related (1) to the scientific knowledge or technical skills required for the practice of pharmacy, or (2) to direct and/or indirect patient care, or (3) to the specific management and operation of a pharmacy practice. All continuing education coursework shall be:

(1) accurate and timely;

(2) presented in an orderly fashion conducive to the learning process;

(3) complete and objective, and not reflecting predominantly the commercial views of the provider or of anyone giving financial assistance to the provider;

(4) specifically applicable and pertinent to the practice of pharmacy; and

(5) based on stated educational goals and objectives.

(d) All providers

(c) Providers shall furnish certificates of completion statements of credit to all participants that complete a continuing education course. enrollees. The certificate statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.

(e)

(d) Each ~~recognized~~ provider shall notify the accreditation agency~~, on forms approved by the board, within~~ at least 15 days in advance of the first time each new ~~C.E.~~ continuing education course is offered or presented.
~~(f) All providers~~
(e) Providers shall maintain records of ~~attendance at or~~ completion of their continuing education courses ~~programs~~ for four ~~(4)~~ years.
(f) Providers shall include the following information in promotional materials regarding continuing education courses:

(1) Provider's name.
(2) The number of hours awarded for completion of the course
(3) The course's date of expiration
(4) The provider number assigned by the accreditation agency.
(5) The name of the provider's accrediting agency.
(6) The learning objectives of the program.
(7) The nature of the targeted audiences that may best benefit from participation in the program.
(8) The speakers and their credentials.

(g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.2. ~~Coursework from Non-Recognized Providers.~~ Board Accredited Continuing Education.

(a) ~~Non-recognized providers or pharmacists~~ Individuals may petition the ~~Board~~ board to allow continuing education credit for specific coursework which is not offered by a ~~recognized~~ provider but meets the standards of Section 1732.3. ~~relevance to pharmacy practice and educational quality, as set forth in subdivision (c) of section 1732.1.~~
(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.3. ~~Coursework Approval for Providers.~~ Requirements for Continuing Education Courses

(a) Unless denied by the accreditation agency upon audit, all coursework offered by ~~California recognized~~ providers ~~is considered as approved in California.~~ may be used to satisfy the continuing education required by section 1732.5 of this Division.
(b) On a random basis ~~established by the Board~~ or in response to ~~complaints about~~ a ~~particular provider or~~ requests by the board ~~Board~~, the accreditation agency shall review

selected coursework. ~~Within 15 days of receipt of written notification, the provider shall submit to the accreditation agency all material deemed necessary by the Committee to review the course.~~ The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section. ~~those defining relevance to pharmacy practice and educational quality stated in Section 1732.1(c).~~

(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.

~~(d) A recognized provider's advertisements for approved coursework shall clearly indicate the provider's name, the coursework's number of hours, date of expiration, the provider number assigned by the accreditation agency and the name of the accrediting agency.~~

(d) Continuing education courses shall comply with the following:

(1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.

(2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.

(3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.

(4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.

(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in section 4232 of the Business and Professions Code and related to one or more of the following:

(A) The scientific knowledge or technical skills required for the practice of pharmacy.

(B) Direct and/or indirect patient care.

(C) The management and operation of a pharmacy practice.

(2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

Note:

Authority cited: ~~S~~sections 4005~~, 4206 and 4232~~, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course ~~coursework~~, each ~~recognized~~ provider shall submit such materials as are required by the accreditation agency.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in ~~S~~section 4234 of the Business and Professions Code and ~~S~~section 1732.6 of this ~~Article~~ Division, each applicant for renewal of a pharmacist license shall submit ~~with the application for renewal~~ proof satisfactory to the board ~~Board that~~, that the applicant has completed 30 hours of continuing education in the prior 24 months. ~~subsequent to the last renewal thereof, he or she has completed 30 hours of approved continuing education.~~
(b) All pharmacists shall retain their certificates of completion for four ~~(4)~~ years following completion of a continuing education course. ~~the program.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4231 and 4232, Business and Professions Code.

§1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for ~~licensure~~ renewal on the grounds of emergency or hardship by applying to the board ~~Board~~ in writing~~, on a form provided for that purpose,~~ setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4234, Business and Professions Code.

§1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board. ~~full Board of Pharmacy~~.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code ~~S~~section 11055) may be partially filled, as defined in paragraph (b), if:
(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code ~~S~~section 1250; or
(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c)When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within ~~fourteen~~ 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original ~~triplicate~~ prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 ~~30~~ days from the date of issuance of the prescription; and

(3) No portion of the prescription is dispensed more than 60 ~~30~~ days from the date of issuance of the prescription; and

~~(4) The original triplicate prescription is forwarded to the Department of Justice in conformity with Health and Safety Code section 11164(a) at the end of the month in which the prescription has been completely filled or in which the prescription has been canceled by death of the patient or otherwise, whichever comes first.~~

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4301, Business and Professions Code; and ~~S~~sections 11055, 11153, 11154, ~~11164,~~ 11166, 11200, Health and Safety Code.

§1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with ~~S~~section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a ~~permit to conduct a~~ pharmacy license is three hundred forty dollars ($340). The fee for the annual renewal of ~~said permit~~ pharmacy license is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).

(b) The fee for the issuance of a temporary license ~~permit~~ is one hundred seventy-five dollars ($175).

(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25). (d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars ($155).

(e) The fee for regrading an examination is seventy-five dollars ($75).

(f) The fee for the issuance of an original pharmacist license is one hundred fifteen dollars ($115).
(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars ($115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents ($57.50).
(h) The fee for the issuance or renewal of a wholesaler's license ~~permit~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is ninety dollars ($90). The penalty for failure to renew is forty-five dollars ($45).
(j) The fees for a certificate of exemption under the provisions of sections 4053~~,~~ or 4054 ~~and 4133~~ of the Business and Professions Code are as follows:

(1) For the application and investigation of the applicant, the fee is seventy-five dollars ($75).

(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).

(k) The fee for the issuance or renewal of a license as an out-of-state distributor ~~manufacturer or wholesaler~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).
(l) The fee for ~~registration as~~ an intern pharmacist license ~~or extension of the registration~~ is sixty-five dollars ($65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars ($10).
(m) ~~The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars ($30).~~ The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars ($60).
(n) ~~The fee for registration and annual renewal of providers of continuing education is one hundred dollars ($100). The penalty for failure to renew is fifty dollars ($50).~~
~~(o)~~ The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
~~(p) The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars ($165).~~
~~(q)~~ (o) The fee for the issuance of a clinic license ~~permit~~ is three hundred forty dollars ($340). The fee for the annual renewal of a clinic license ~~said permit~~ is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).
~~(r) The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars ($170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents ($87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents ($43.75).~~

Note:

Authority cited: ~~S~~sections 163.5 and 4005, Business and Professions Code. Reference: ~~S~~sections 163.5, 4005, 4110, 4112(h), 4120, ~~4130,~~ 4196, 4200~~(c)~~, 4400~~(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w)~~, 4401 and 4403, Business and Professions Code.

§1750. Fee Schedule--Health and Safety Code.

~~The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars ($100). The penalty for failure to renew is twenty-five dollars ($25).~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code; and ~~S~~section 11127, Health and Safety Code. Reference: ~~S~~s ection 11127, Health and Safety Code.

Article 8. ~~Rules of Professional Conduct~~ Prohibitions and Discipline

Attachment 2

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Add Section 1713

§1713 Receipt and Delivery of Prescriptions

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.[1]
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.[2]
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use a device to dispense refilled prescriptions when the pharmacy is not open provided:

(1) The device is located at the same address or adjoining the licensed premises.
(2) The device has a means to identify the patient and only release that patient's prescriptions.
(3) The device is secure from access by unauthorized individuals.
(4) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(5) The pharmacy is responsible for the prescriptions stored in the device.

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the

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[1] Moved from 1717 (e).
[2] Moved from 1717 (e).

prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.